

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

<p>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</p> <p>THIS DOCUMENT RELATES TO:</p> <p>ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION</p>	<p>Master File No. 2:12-MD-02327 MDL 2327</p> <p>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</p>
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**ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO
EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DOUGLAS GRIER, M.D.**

Douglas Grier, M.D. is an experienced urologist specializing in female pelvic medicine and surgery. He has performed over 1,000 mesh surgeries to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP), including those utilizing TVT products (TVT, TVT-O, and TVT-Secur), Prolift, and Prolene Soft Mesh. Dr. Grier has educated and trained hundreds of surgeons in these techniques. Dr. Grier also has treated mesh complications and performed mesh revisions. He has performed research in the field of incontinence and bladder disorders, and contributed to studies on the use of TVT abdominal guides and the TVT world registry. Throughout his career, he has kept abreast of issues in his field by review and study of the relevant literature.

Despite this extensive career, Plaintiffs seek to exclude Dr. Grier's opinions that: (1) the designs of TVT products, Prolift, and Prolene Soft Mesh are safe and effective for use in patients; (2) the benefits of the TVT products, Prolift, and Prolene Soft Mesh outweigh their risks based in part on his complication rate with polypropylene transvaginal mesh devices; and

(3) the Instructions for Use (IFU) for the TVT products, Prolift, and Prolene Soft devices adequately warn of their risks. Plaintiffs' motion should be denied because:

- **Dr. Grier is qualified to offer the challenged opinions.** Dr. Grier's extensive clinical and research background make him well qualified to give opinions on the safety and efficacy of TVT products, Prolift, and Prolene Soft Mesh, as well as the IFUs for these products.
- **Dr. Grier's design opinions are supported by a reliable methodology.** Relying upon clinical experience and review of relevant literature is a reliable method for forming opinions on the safety and efficacy of the TVT products, Prolift, and Prolene Soft Mesh.
- **Dr. Grier's clinical experience is admissible to support his risk/benefits opinions.** Dr. Grier's extensive clinical experience, including his observations of the incidence of complications he sees in his practice, supports his opinion that the benefits of TVT products, Prolift, and Prolene Soft Mesh outweigh their risks.

Plaintiffs' challenges to Dr. Grier's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Grier's Opinions on the Safety and Efficacy of the Designs of the TVT Products, Prolift, and Prolene Mesh Are Admissible.

A. Dr. Grier Is Qualified to Provide Safety and Efficacy Opinions.

A physician's "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on [product design], notwithstanding his lack of expertise in the particular areas of product design or biomaterials." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013) (finding Dr. Shull qualified, but excluding his design opinion on reliability grounds). Further, a physician's "experience removing polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him" to give product design opinions. *Winebarger v.*

Boston Scientific Corp., No. 2:13-cv-28892, 2015 WL 1887222, at *6 (S.D.W. Va. Apr. 24, 2015).

Dr. Grier has the necessary qualifications to opine that the designs of the TVT products, Prolift, and Prolene Soft Mesh are safe and effective for use in patients. Specifically, Dr. Grier is a urologist with an expertise in urologic surgery and the materials used in urologic surgery. Ex. 1, Grier 3/22/16 Dep. Tr. 329:6-10. He has specialized in female pelvic medicine and surgery for over 15 years. *Id.* at 82:14-19; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 1-2. Before this litigation, at least 50 percent of Dr. Grier’s practice was related to the treatment of SUI and POP. Ex. 1, Grier 3/22/16 Dep. Tr. 145:23-146:1.

He has performed native-tissue surgical procedures and surgical procedures involving mesh, including Ethicon's TVT and TVT-O, TVT-Abbrevio, and TVT-Secur mid-urethral slings, AMS Monarch, Uretex by Bard, Vesica in situ sling, Stamey cystourethropexy, MMK, and Burch procedures. Ex. 1, Grier 3/22/16 Dep. Tr. 333:24-334:9; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. All told, he has performed over 1,000 TVT procedures, including procedures implanting the TVT-O, TVT-Exact, and TVT-Abbrevio. Ex. 1, Grier 3/22/16 Dep. Tr. 31:15-21, 333:24-334:9. He also has performed surgeries utilizing Prolift and Prolene Soft mesh. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 2; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 2. Besides performing surgical implant procedures, he also treats mesh complications and has performed mesh-removal surgeries for exposed TVT mesh. Ex. 1, Grier 3/22/16 Dep. Tr. 142:16-20, 143:20-144:13, 146:5-11.

In addition to his clinical background, Dr. Grier also has an extensive teaching and research background. He has taught over 300 courses for advanced surgical training of physicians for conditions such as stress urinary incontinence and pelvic organ prolapse. Ex. D to

Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 2. And he has conducted research in the field of incontinence and bladder disorders, and has contributed to studies on the use of TVT abdominal guides and the TVT world registry published in the Journal of Urology in 2011. Ex. D to Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. To keep abreast of issues in his field, he regularly reviews the relevant medical literature and has done so for the past ten to fifteen years. Ex. 1, Grier 3/22/16 Dep. Tr. 50:14-20.

Dr. Grier's extensive experience with pelvic-floor disorders and the use of mesh to treat these disorders uniquely qualifies him to render opinions on the safety and efficacy of mesh product design. Although he is not an engineering expert, Dr. Grier is well versed on the use and placement of vaginal mesh based on his extensive training and experience. Ex. 1, Grier 3/22/16 Dep. Tr. 67:14-17. The law does not require Dr. Grier to have expertise designing mesh products to be qualified to give an opinion on the safety and efficacy of these products. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612; *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W.Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products)

B. Dr. Grier Utilized a Reliable Methodology in Forming His Safety and Efficacy Opinions.

This Court has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the risk/benefit profile of polypropylene mesh. *Winebarger*, 2015 WL 1887222, at *7. Dr. Grier seeks to offer the same kind of opinion here—*i.e.*, that the benefits of the TVT, Prolift, and Prolene Soft Mesh products outweigh their risks. He bases that opinion on his extensive clinical experience performing hundreds of SUI and POP mesh surgeries and removing mesh devices from patients. Ex. 1, Grier 3/22/16 Dep. Tr. 143:20-

144:13, 145:23-146:11, 333:24-334:9; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 1-2; Ex. C to Pls.’ Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 1-2; Ex. D to Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 1-2. Dr. Grier’s opinion is also based on his education, training, teaching, extensive review of high-level, peer-reviewed literature (including comparing complications discussed in the literature with those seen in his practice), studies, professional society position statements, and ongoing discourse with colleagues. Ex. 1, Grier 3/22/16 Dep. Tr. 331:12-332:17, 336:11-20, 338:18-351:6; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 7-19, 22-24; Ex. C to Pls.’ Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 6-15, 17-19; Ex. D to Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 11-23, 25-30; Ex. E to Pls.’ Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 11-27, 31-35.

There is no requirement under *Daubert* that Dr. Grier review internal company design documents for his methodology to be reliable as Plaintiffs argue. Nor has this Court ever required as much. Although Plaintiffs rely on *Winebarger* to support their argument, that reliance is misplaced. In that case, Dr. Shull sought to opine that the company had failed to follow its own internal protocols and that those protocols were lacking, even though he had never seen any standard operating procedures for the company’s medical device development or any of the internal design protocols. *Winebarger*, 2015 WL 1887222, at *14. Dr. Shull’s methodology was thus lacking “a necessary piece of data” and unreliable “regardless of the literature he has reviewed or the experience he has gained” because his methodology failed to include a review of the documents that would support his internal-protocols opinion. *Id.*

By contrast, Dr. Grier here is not attempting to testify that Ethicon followed its own internal design protocols or that they were otherwise adequate. As such, his opinion does not require a review of internal design protocols, design history files, or design failure modes and

effects analyses (dFMEA). Indeed, although Dr. Grier reviewed some of these documents, he explained that design documents are not clinically relevant to him and that dFMEAs do not fall within any level of the hierarchy of scientific evidence. Ex. 1, Grier 3/22/16 Dep. Tr. 44:20-24, 65:15-66:9, 136:9-23, 331:2-11. As a result, these are not the type of materials upon which Dr. Grier would rely to form his clinical opinion on the safety and efficacy of mesh products for use in patients.

At bottom, Dr. Grier has the expertise required to provide opinions on the safety and efficacy of the TVT, TVT-O, TVT-Secur, Prolift, and Prolene Soft Mesh designs, and has provided a reliable basis for those opinions. This opinion testimony is admissible.

II. Dr. Grier's Testimony About His Clinical Experience with TVT Products, Prolift, and Prolene Soft Mesh Is Admissible to Support His Opinion on the Safety and Efficacy of These Products.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court, in particular, has made clear that a physician can draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See Tyree*, 54 F. Supp. 3d at 585 (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). It has found the same with respect to an expert offering a risk/benefit opinion. *See Winebarger*, 2015 WL 1887222, at *7.

As explained, Dr. Grier offers the same opinions here based on the same methodology. He seeks to testify that the benefits of the TVT, Prolift, and Prolene Soft Mesh products outweigh their risks and he bases that opinion on his extensive clinical experience, as well as his review of the relevant medical literature over the course of his career. Ex. 1, Grier 3/22/16 Dep.

Tr. 331:12-332:17, 334:10-13, 335:7-17, 336:11-20, 338:18-351:6; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 1-2, 7-19, 22-24; Ex. C to Pls.’ Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 1-2, 6-15, 17-19; Ex. D to Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 1-2, 11-23, 25-30; Ex. E to Pls.’ Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 1-2, 11-27, 31-35. Dr. Grier’s support for this opinion includes the complications he has seen in his practice with TVT, TVT-O, or TVT-Secur slings, which are similar to what is reported in the medical literature. Ex. 1, Grier 3/22/16 Dep. Tr. 334:10-13.

Plaintiffs take issue with Dr. Grier’s opinion about incidence of complications he sees in his practice because it is not supported by any statistical analysis, formal study, or separate “list” for “tracking data.” *See* Pls.’ Mem. (Dkt. 2024) at 12. Plaintiffs cite no authority that this is required under *Daubert*. Instead, what *Daubert* requires, and what Dr. Grier did here, was to treat patients that have experienced complications, record those complications in medical records, and report on the incidence of those complications that he has seen in his practice. Contrary to Plaintiffs’ argument, Dr. Grier follows his patients, the reason for any mesh removal, and the product being removed through annual appointments and medical records. Ex. 1, Grier 3/22/16 Dep. Tr. 143:3-13, 336:3-10. Any lack of separate “tracking data” does not render Dr. Grier’s clinical experience unscientific or unhelpful.

A physician offering opinions based on complications the physician has observed in his or her clinical practice uses a reliable methodology, and is consistent with the analysis this Court employs for reliability. *Winebarger*, 2015 WL 1887222, at *7. Indeed, this Court has rejected the argument that opinions on mesh complications are unreliable because they are based on personal experience and review of medical literature. *See Eghnayem*, 57 F. Supp. 3d at 714 (denying

request to exclude Dr. Walmsley's general opinions on complication rates based on his personal clinical experience and review of the medical literature).

At bottom, Dr. Grier is sufficiently qualified and the opinions he seeks to offer result from a reliable methodology. It would make no sense, and is contrary to the Rules of Evidence, to allow Dr. Grier to draw upon clinical experience and medical literature to provide a risk/benefit opinion, but then prevent him from explaining to the jury how he reached that opinion.

III. Dr. Grier Is Qualified to Provide an Opinion on the Adequacy of the IFUs for the TVT Products, Prolift, and Prolene Soft Mesh.

“[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings.” *Winebarger*, 2015 WL 1887222, at *15. A physician is qualified to make a comparison between “the risks he perceives that the [device] poses to patients” and whether the labels “convey these risks to physicians.” *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

Dr. Grier seeks to offer such an opinion here. In addition to his clinical experience with mesh surgical techniques and review of IFUs, Dr. Grier relies on his review of complications reported in the medical literature, statements of leading medical societies, FDA Device Labeling Guidance No. G91-1 (dated March 8, 1991), discussions with other surgeons, and general knowledge as a pelvic-floor surgeon. Ex. 1, Grier 3/22/16 Dep. Tr. 326:23-330:20, 332:13-333:23; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 19-22; Ex. C to Pls.’ Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 23-25; Ex. E to Pls.’ Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 28-30. Based

on this support, Dr. Grier has formed the opinion that exposure/erosion is the only risk unique to mesh devices, and that degradation, shrinking, contraction or pore collapse, roping or curling, particle loss, cytotoxicity, excessive inflammatory response, and carcinogenicity are **not** risks associated with mesh devices. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 17, 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 18-21, 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 19-20, 34. Dr. Grier further concludes that chronic pain and dyspareunia are generalized risks of mesh surgery, and therefore need not be warned about. Ex. 1, Grier 3/22/16 Dep. Tr. 19:12-21; 319:8-14, 332:18-25; 337:9-12. As a result, Dr. Grier concludes that there are no additional unique risks that should be included in the IFU warnings. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 28-29, 34. Dr. Grier's opinion is consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.").

This Court's rulings in *Tyree* and *Bellew* are distinguishable. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584 (S.D.W. Va. 2014), as amended (Oct. 29, 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). While a single physician's

experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Grier has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Grier's conclusion goes to weight, not admissibility.

Dr. Grier has the clinical experience needed to form an opinion about the warnings accompanying the mesh devices he uses in his patients. Ex. 1, Grier 3/22/16 Dep. Tr. 329:6-330:5. In his practice, he reviews IFUs before using a new medical device. *Id.* at 329:14-23. Dr. Grier has also performed hundreds of SUI and POP mesh surgeries and removed dozens of mesh devices from patients. *Id.* at 143:20-144:13, 145:23-146:11, 333:24-334:9; Ex. B to Pls.’ Mot. (Dkt. 2022-2), Grier Prolift Report at 2; Ex. C to Pls.’ Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 2; Ex. D to Pls.’ Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. Based on his clinical perspective and review of the medical literature, he is qualified to give opinions about warnings.

At bottom, Dr. Grier is qualified to provide opinions on the IFUs and has employed a sufficiently reliable methodology. His opinion on the adequacy of the TVT, TVT-O, TVT-Secur, Prolift, and Prolene Soft Mesh IFUs is therefore admissible.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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EXHIBIT 1

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4
5 IN RE: ETHICON, INC. PELVIC REPAIR)
6 SYSTEM PRODUCTS LIABILITY LITIGATION)
7 _____
8 THIS DOCUMENT RELATES TO THE)
9 FOLLOWING CASES IN WAVE 1 OF 200:)
10) 2:12-MD-02327
11 Barbara A. Hill)
12 Case No. 2:12-cv-00806) MDL No. 2327
13)
14 Constance Daino)
15 Case No. 2:12-cv-01145)
16) Joseph R. Goodwin
17 Monica Freitas) U.S. District Judge
18 Case No. 2:12-cv-01146)
19)
20 Patricia Ruiz)
21 Case No. 2:12-cv-01021)
22)
23 Pamela Gray Wheeler)
24 Case No. 2:12-cv-00455)
25)
26 Rebekah Bartlett (Pratt))
27 Case No. 2:12-cv-01273)
28)
29 Dawna Hankins)
30 Case No. 2:12-cv-00369)
31)
32 Patricia Tyler)
33 Case No. 2:12-cv-00469)
34
35

DEPOSITION OF DOUGLAS GRIER, M.D.

March 22, 2016

Seattle, Washington

1 A Yes.

2 Q And the TVT Exact uses only laser cut mesh; is that
3 correct?

4 A I don't know that to be true. I don't know whether or
5 not they offer both mechanical or laser.

6 Q Okay. You just don't know, as you sit here?

7 A I don't know.

8 Q And the TVT Abbrevio is the new version of TVT-O; is that
9 fair?

10 A Yes.

11 MR. KOOPMANN: I object just to this
12 line of questioning as it relates to other products, for
13 the record. This is supposed to be the TVT, TVT-O, and
14 TVT-Secur, so --

15 Q (By Mr. DeGreeff) Okay. TVT Abbrevio uses only laser cut
16 mesh; correct?

17 A I think that's correct.

18 Q Doctor, do you have an understanding of why mechanically
19 cut mesh isn't used in those products?

20 A Well, I think the reason that there was a change in the
21 product to laser from mechanical was to smooth out the
22 edges so that it may be a little less irritating and
23 perhaps have less of an inflammatory response of the
24 tissues.

25 But clinically there's no difference between the

1 two. I've never noticed any difference in the placement
2 or in the results of whether the sling was mechanical or
3 laser cut. And --

4 Q And, Doctor, do you -- is that something you track within
5 your office?

6 A I track all my patients in the office.

7 Q Do you track whether you're putting in laser cut or
8 mechanical cut mesh?

9 A Well, if I'm putting in a TVT Abbrevio, then I assume that
10 it's laser cut.

11 Q Okay. What if you're putting in one of the other
12 products?

13 A I don't track it because I don't find it clinically
14 relevant.

15 Q Okay. So it's not something you track within your office
16 whether you're putting in mechanically or laser cut mesh?

17 A I don't actively track it because it's not -- it's -- I
18 have no concern of one mesh cut or the other because I
19 consider them equivalent. My experience with them is
20 equivalent. But I do know that if I'm putting in a TVT
21 Exact or an Abbrevio, that it's laser cut.

22 Q Okay. I guess my question's pretty simple. Do you or do
23 you not track whether you're putting in a laser cut or
24 mechanical cut mesh?

25 MR. KOOPMANN: Object to form. Asked

1 and answered.

2 THE WITNESS: I don't track it.

3 Q (By Mr. DeGreeff) And I think you mentioned that the
4 reason for the switch from laser cut to mechanical was
5 because the mechanical cut mesh can cause more
6 irritation, given it's not as smooth on the edges?

7 A That's the theoretical consideration, yes.

8 Q And, Doctor, given that you don't track whether you're
9 putting in laser or mechanical cut mesh, as you sit here,
10 you can't say whether there's -- whether you're having an
11 equivalent number of complications with one versus the
12 other; correct?

13 A I know of no literature that shows any comparative
14 difference between the two cuts, so I'm not aware that
15 there is a problem for me to track. And in all my
16 colleagues around the country, I know of no one who's
17 tracking the results between mechanical and laser cut
18 because there's no clinical significance because no one
19 has identified there to be a problem.

20 MR. DEGREEFF: Can you read back my
21 question?

22 (Question on Page 32, Line 8
23 read by the reporter.)

24 THE WITNESS: Yes.

25 Q (By Mr. DeGreeff) Is there -- is laser cut stiffer than

1 Q Any documents in there specifically that you remember
2 reading front to back?

3 A At this -- well, the IFU is in there, so I have read that
4 in the past front to back. I read the historical
5 documents about how TVT first was developed. And those
6 are the ones that I remember in particular. There are a
7 couple PowerPoint presentations that I probably was in --
8 present for or were delivered to me.

9 Q Doctor, how many of these -- how many of these 34
10 documents do you think you actually reviewed in full?

11 MR. KOOPMANN: Object to form.

12 THE WITNESS: I can't give you an
13 exact answer to that, but if you look through it, they're
14 historical documents, so I don't -- I didn't spend much
15 time at all with the Internet discussions between the
16 Ethicon people and the corporation.

17 Q (By Mr. DeGreeff) Did you -- in rendering your opinions,
18 did you rely at all on internal company documents?

19 A No.

20 Q Why not?

21 A I don't find them necessarily relevant.

22 Q Why are they not relevant?

23 A Well, because a lot of it has to do with research and
24 development early on in the development of the products,
25 and quite frankly, it's not -- I don't find it relevant

1 for me in rendering an opinion.

2 Q Did you review any of the design documents for the
3 product?

4 MR. KOOPMANN: Objection. Form.

5 THE WITNESS: I don't recall design
6 documents. You mean the original design of the -- of the
7 mesh?

8 Q (By Mr. DeGreeff) Yeah, the design documents, the
9 internal design documents for the mesh product?

10 A Well, if you could show me one, I could tell you whether
11 I've reviewed it or not.

12 Q Well, do you know what I'm talking about when I say
13 design documents?

14 A Not precisely, no.

15 Q Okay.

16 A Are you talking about before it was submitted to the FDA?

17 Q Well, have you reviewed the design device file?

18 MR. KOOPMANN: Objection. Form.

19 THE WITNESS: I don't recall.

20 Q (By Mr. DeGreeff) As you sit here, do you remember
21 recalling any -- reviewing any internal Ethicon documents
22 specifically relating to design of the TVT products?

23 A I'm sure I've looked at several, but none come to mind
24 specifically.

25 Q Okay. If you think you looked at several, what did those

1 documents look like? What did they tell you?

2 A Oh, I don't recall. I looked at them prior to the Perry
3 trial, I would imagine.

4 Q Okay. So -- and the Perry trial was about the TVT
5 Abbrevio; correct?

6 A Correct.

7 Q And we're not here -- you're not rendering any opinions
8 in this -- at this point generally about the TVT Abbrevio?

9 A No.

10 Q So my question is about design documents that would be
11 relevant to the products that we're here about. Do you
12 remember reviewing any of those design documents?

13 A Not specifically.

14 Q Well, not specifically. Do you remember reviewing any at
15 all?

16 A If you put one in front of me, I can tell you whether I
17 have or not.

18 Q Well, Doctor, you've got them -- are they on your
19 reliance list?

20 A Some may be.

21 Q And did you review everything on your reliance list?

22 A I've -- in a general sense, yes. Specifically, I mean,
23 there's a lot of documents, and some I may have just
24 looked at the title and then what the conclusions were,
25 and if something was interesting in there, I would go

1 A This binder contains multiple studies on TVT. It has my
2 general report in it, and it has articles that I reviewed
3 for my opinion. It has the different specialty body
4 position papers on the use of mesh and different papers
5 comparing Burches. It has an article on abdominal wall
6 hernia repair using mesh.

7 Q And, Doctor, you don't have to go through every one of
8 them in general. I'm just kind of trying to figure out
9 in general what categories of documents are in there.

10 A Well, scientific papers. Papers that are produced by the
11 different specialty bodies, like AUGS and SUFU, and
12 multiple articles and abstracts. There's an article on
13 the elongation characteristics of TVT Prolene. There's
14 an expert report on mechanical mesh versus laser cut.
15 There's an IFU for TVT-Secur.

16 There is a research and development memorandum on
17 mesh for TVT-O. There is some comment on FDA hearing in
18 2011, the FDA executive summary. A Cochrane review of
19 midurethral slings. Long-term efficacy of TVT --

20 Q Maybe we can do this. Is this all articles and clinical
21 studies? Is that essentially what's in there?

22 A Yes.

23 Q Okay. And that -- is this a binder that you prepared,
24 yourself?

25 A No.

1 Q Who prepared that binder for you?

2 A The attorneys, after sending me these articles for
3 review.

4 Q Are those all articles that the attorneys sent you?

5 A Yes.

6 Q Okay. Those weren't articles that you did a systematic
7 review and found them yourself?

8 MR. KOOPMANN: Objection. Form.

9 THE WITNESS: Well, I'm looking at one
10 that I wrote, that I was -- I participated in. There are
11 just multiple studies.

12 Q (By Mr. DeGreeff) That wasn't my question.

13 A Oh, sorry.

14 Q Did you do an independent systematic review and decide on
15 which articles you wanted to review in rendering your
16 opinions?

17 A Not this extensive. I've read the literature for the
18 last ten, fifteen years, and so I keep abreast of it. So
19 not every article is in journals that I have -- that I
20 get.

21 Q Okay. So I think the answer to my question is no, you
22 didn't do an independent systematic review for the
23 literature that's on your reliance list?

24 A Yes, that's correct.

25 Q And you didn't put together that binder. Defense counsel

1 did.

2 A Correct.

3 Q And defense counsel selected the articles that are in
4 that binder?

5 MR. KOOPMANN: Objection. Form.
6 Misstates the record.

7 MR. DEGREEFF: I don't think it does.

8 THE WITNESS: Well, I don't know what
9 they -- how they selected them.

10 Q (By Mr. DeGreeff) You --

11 A They're not all positive articles.

12 Q Well, that's true too, but you didn't select all of
13 those; correct?

14 A Correct.

15 Q Those were selected for someone else -- by someone else
16 for you?

17 A Yes.

18 Q And they were sent to you by defense counsel?

19 A Yes.

20 Q And did you review all of the articles in that binder?

21 A The majority of them, yes.

22 Q Okay. Did you review -- did you rely on all the articles
23 in that binder?

24 A I relied on all those that I reviewed.

25 Q And which ones -- did you review those that were -- that

1 A My memory, last time I saw him was when I did a cadaver
2 lab with about ten surgeons from around the country on
3 the TVT-O. It was our first experience with the TVT-O,
4 and we were using the device prior to having used it in
5 our practices.

6 And another article by Leval and Waltigney on the
7 one-year follow-up on TVT-O. And Leval's white paper on
8 the TVT-O.

9 Q Who is Leval?

10 A Jean Leval is a Belgian urologist out of Liege, Belgium,
11 as I recall, and he was the developer of the inside-out
12 approach for transobturator slings.

13 Q Do you know Dr. Leval?

14 A I met him once. He does not speak English. Talked to
15 him through a -- an interpreter.

16 Q You met -- did you meet Dr. Leval and Dr. Weisberg at
17 Ethicon events?

18 A Yes. Yes.

19 Q So fair to say that that binder you're looking at
20 contains just a bunch of materials that are on TVT-O?

21 A Yes.

22 Q And did you put that binder together, yourself?

23 A No.

24 Q Was that put together for you by defense counsel?

25 A Yes.

1 Q Did defense counsel select the documents that went into
2 that binder?

3 A Yes.

4 Q Have you reviewed all of the documents in that binder?

5 A Well, I've reviewed them -- a lot of them I've reviewed
6 before they ever were put in the binder, before I was
7 ever asked to review them.

8 Q Okay. So my question was a little different than that.

9 Have you reviewed -- and I don't care when you
10 reviewed them. Have you reviewed all of the lit- -- all
11 of the documents that are in that binder?

12 A Well, no. The ones I haven't reviewed were the pre-FDA
13 design documents, which are very tedious, and I didn't
14 find relevant.

15 Q So fair to say, you did not review the design documents
16 that were relied on by Ethicon for approval by the FDA?

17 MR. KOOPMANN: Objection to form.

18 THE WITNESS: That's true.

19 Q (By Mr. DeGreeff) Anything else?

20 A Well, there's just a bunch of minutes and discussions by,
21 I guess, engineers within the -- within the company on
22 the product specifications and the launch of the product.

23 Q And did you review those?

24 A I did not.

25 Q Why not?

1 A Well, because I don't find it relevant.

2 Q And that's the -- those are memos done by the engineers
3 who designed the product?

4 A Correct.

5 Q Why did you not find that relevant?

6 A Well, because it's tremendously tedious, and it's not
7 clinically relevant. It was how they developed the
8 product and -- the device, and it's kind of too technical
9 for my interest.

10 Q And you didn't -- so you didn't review that in rendering
11 your opinions?

12 A No.

13 Q Did you review any documents related to the -- kind of
14 the -- what you referred to as the tedious portion of the
15 design of the -- of the document and getting FDA
16 approval?

17 MR. KOOPMANN: Objection. Form.

18 THE WITNESS: There may be a few that
19 I reviewed.

20 Q (By Mr. DeGreeff) Which ones? Any as you sit here that
21 you remember?

22 A My patients' list at home.

23 Q I was wondering how that got in there.

24 A Yeah, that just got -- it fell in.

25 The ones I reviewed were -- see, a lot of this is

1 just -- it's not even in English. It's the documents
2 that are -- came out of Belgium that aren't even
3 translated, so I certainly didn't read those.

4 The others were just kind of how the sheath was
5 developed, not the actual sling, but the sheath that
6 helps place it. So these -- and, you know, this TVT flow
7 of process qualifications, I looked at it. It's a very
8 technical engineering document on the product production.
9 I'm not an engineer, so it's not relevant to me. There's
10 just a lot of that. How to package it, what kind of box
11 it should be in, things --

12 Q So you're not an engineering expert; correct?

13 MR. KOOPMANN: Objection. Form.

14 THE WITNESS: I'm not an engineering
15 expert, but I am an expert on the use and placement and
16 management of vaginal mesh because that's what I've done
17 a lot of.

18 Q (By Mr. DeGreeff) That doesn't make you -- you are
19 not --

20 A It does not make me an engineer.

21 Q You're not holding yourself out as an expert in the field
22 of engineering, are you, Doctor?

23 A No, of course not.

24 Q And fair to say, you're not holding yourself out as an
25 expert in the field of transvaginal mesh design?

1 MR. KOOPMANN: Objection. Form.

2 THE WITNESS: I will say no. I will

3 say, though, that -- that all of us give feedback to the

4 companies that we use mesh, as to what might be better

5 about it.

6 Q (By Mr. DeGreeff) I think we agree. My question is

7 pretty simple. Yes or no, are you holding yourself --

8 yes, no, or you can't answer. Are you holding yourself

9 out as an expert on the design of transvaginal mesh

10 products?

11 MR. KOOPMANN: Objection. Form.

12 Asked and answered.

13 THE WITNESS: Do I answer?

14 MR. KOOPMANN: Go ahead, yeah.

15 THE WITNESS: So I am not a product

16 engineer that has designed mesh products. However, I

17 have used them, and I have opinions about what -- what is

18 good or bad about a particular product, which I have

19 expressed to multiple companies when asked. So -- but I

20 am not an engineer.

21 Q (By Mr. DeGreeff) Let's try this again. Doctor, yes,

22 no, or you cannot answer my question as it's phrased:

23 Are you holding yourself out as an expert in the design

24 of transvaginal mesh products?

25 MR. KOOPMANN: Same objection.

1 A Yes.

2 Q Did you submit it to the -- to the --

3 A FPRMS, yes.

4 Q -- FPRMS?

5 And so given that you had that role, you still don't
6 remember what that number was?

7 A Oh, it was the number of all the surgeries that you've
8 done. No, I have no idea what that number is.

9 Q All of the surgeries that you've done since when?

10 A Well, in a six-month -- in a six-month period, but that's
11 all -- that's general urology, female urology,
12 whatever -- whatever surgical cases I was doing.

13 Q You also treat males as part of your practice; correct?

14 A Correct.

15 Q What percentage of your practice deals with treating men?

16 A Roughly 50 percent.

17 Q Are you a member of AUGS?

18 A No.

19 Q Why not?

20 A Well, I'm a urologist, and so the urologic focus for
21 female urology is SUFU, society of uro-gynecon- --
22 urology and gyne- -- and -- female urology. And I'm a
23 member of the AUA, but I'm not a member of AUGS. I have
24 gone to several AUGS meetings in the past. The last one
25 was this last October.

1 Q And what does AUGS stand for?

2 A American Urogynecology Society. If you want me to give
3 you kind of a history of urogynecology, I can.

4 Q No, that's okay.

5 You've got teaching positions listed on your -- on
6 Exhibit 2, which is your CV, on the second page.

7 A Yes.

8 Q Let's kind of talk about those. The first one is Ethicon
9 Endosurgical Institute; correct?

10 A Yes.

11 Q And that obviously is something that is through Ethicon,
12 the defendant in this case; correct?

13 A Correct.

14 Q How long have you been teaching for Ethicon Endosurgical
15 Institute?

16 A Well, I started in the '90s, and then probably the last
17 course I gave, I don't know the year. 2013 perhaps.

18 Q So you were doing that for roughly 15, 16 years?

19 A Yes.

20 Q And who takes those courses?

21 A Urologists and gynecologists take those courses.

22 Q And were you paid for those courses -- to give those
23 courses?

24 A Yes.

25 Q And Ethicon paid you for that?

1 A Yes.

2 Q And was that done under a contract with Ethicon?

3 A Yes.

4 Q Would that be --

5 A Annual contracts.

6 Q It would be a one-year rolling contract?

7 A Uh-huh.

8 Q And was that -- was that pursuant to what I've seen
9 called as the consulting agreement?

10 A Yes.

11 Q And that's not a course that's taught for any college?

12 A No, no. But over the years, I have taught courses at
13 medical schools, in medical schools, and have taught
14 urologists who are academics how to do these procedures.

15 Q And there's no continuing education given for taking an
16 Ethicon Endosurgical Institute course, is there?

17 A No. And the reason being is that they don't charge the
18 participants to go to the courses, so that because
19 they're -- because they're there without a tuition, they
20 don't -- they're not allowed to grant CME. Because, to
21 grant CME, it has to go through a national body that
22 credentials.

23 Q The question was a little different than that, a little
24 more simple than that.

25 There's no continuing education given for Ethicon

1 in studies on the inventor's device?

2 A Oh, again, I have no idea. How would I know that
3 information? I've not heard it.

4 Q Do you think they should?

5 A Should prevent? No.

6 Q Do you know whether Ethicon has any policies in place
7 that prohibit inventors from participating in studies on
8 the inventor's device?

9 A I'm not aware.

10 Q Do you think they should?

11 A It's -- I don't have an opinion.

12 Q It doesn't matter to you?

13 A No.

14 Q Doctor, are you aware of how long it took the -- it took
15 Ethicon to get the TVT-O product to market?

16 A I don't recall the timeline.

17 Q Doctor, what is Provencia?

18 A I don't know.

19 Q Do you know what a failure modes and effect analysis is?

20 A That sounds like an engineering design study to look at
21 physical properties of different products/materials.

22 Q Have you ever been involved in one of those analyses?

23 A No.

24 Q What should be in a failure modes and effects analysis?

25 MR. KOOPMANN: Objection. Form.

1 THE WITNESS: Well, can you give me a
2 product or material that you want to apply it to?

3 Q (By Mr. DeGreeff) Mesh. What should be in a failure
4 mode designs effect analysis for mesh?

5 MR. KOOPMANN: Objection. Form.

6 THE WITNESS: Well, one would be what
7 its tensile strength is, elongation overload. Those
8 would be the main ones.

9 Q (By Mr. DeGreeff) Have you ever -- did you review the --
10 any of the FMEAs in this case?

11 A I've seen some, yes.

12 Q For transvaginal mesh?

13 A Uh-huh.

14 Q Which ones?

15 A Oh, I think Guenther is one. Moalli has some. But
16 there's Dietz study from Australia that described the
17 bench loading and elongation.

18 Q You're talking about articles and studies; correct?

19 A Yes. But I -- as far as the -- you mean as far as
20 corporate documents in terms of what they did prior to
21 the product being released?

22 Q Yes.

23 A I would glance over them and not -- and not read them.

24 Q All potential hazards should be in the failure modes
25 effects analysis for TVT; correct?

1 MR. KOOPMANN: Objection. Form.

2 THE WITNESS: Again, I don't know what
3 that means.

4 Q (By Mr. DeGreeff) You don't know what a design failure
5 modes effect analysis is?

6 A Well, I know -- I know what the term is, but when you're
7 saying -- there's a difference between in vivo and ex
8 vivo. If you're talking about bench testing products
9 that the stresses that are put on them are greater than
10 the physiologic stress in the body, I don't think those
11 are relevant.

12 I mean, it's fine to do the studies to get a sense
13 of what the burst strength is of mesh, but it's never
14 going to be seen after it's deployed.

15 Q And you don't find those studies relevant, or those
16 relevant?

17 A Well, it has a relevance, but it doesn't have a high
18 significance.

19 Q You don't find them significant?

20 A It has a significance. I can't -- I'm not going to give
21 you a degree of significance.

22 Q You didn't rely on them in giving your opinions in this
23 case; fair?

24 A Well, when I looked at them, I want to make sure that the
25 stressors of these meshes, after they're deployed in the

1 there was a surgical misadventure and, say, the mesh was
2 placed through the wall of the bladder, then I would have
3 to go after all that area that was involved.

4 But there's no reason to chase all of it out of the
5 body because it's -- it's biologically inert where it is
6 and doesn't need to be done.

7 Q (By Mr. DeGreeff) Do you believe that the mesh used in
8 TVT-R is biologically inert?

9 A I think the -- there's a local inflammatory effect
10 initially, which induces fibrosis, some scarring, some
11 collagen deposition, angiogenesis into the -- into the
12 monofilament, and then it settles down over time.

13 Q So you believe that long-term the -- the transvaginal
14 mesh used in the TVT products is biologically inert?

15 MR. KOOPMANN: Objection. Form.

16 THE WITNESS: I don't know your
17 definition of inert, but I would use the word quiet. I
18 have patients who are out 15 years from slings that I
19 have done and I've examined them and they're asymptomatic
20 and they have great results, and they're not concerned
21 with the sling in their body. It's not bothering them.

22 Q (By Mr. DeGreeff) Doctor, what's the definition of
23 inert?

24 A Well, inert is nonactive.

25 Q So your definition of inert is nonactive?

1 A Yeah. That there's nothing going on.

2 Q So you believe that long-term transvaginal mesh is
3 nonactive within a woman's body?

4 A In the vast majority of cases, I would say yes.

5 Q So when you remove mesh, you sometimes make the decision
6 to leave portions of the mesh in because you believe
7 long-term it's nonactive within a woman's body?

8 A Well, the only reason to remove a portion of mesh is if
9 they are symptomatic in that area. So if one area
10 there's a trigger point and they have pain and they
11 haven't responded to conservative measures, you can
12 remove the sling in that location, but you could leave
13 the contralateral side alone if it's not bothering them.
14 In fact, if you leave the majority of the sling in place,
15 there's a good chance they'll remain continent.

16 Q So, Doctor, you have done TVT-R removal surgeries,
17 correct, whether it was removing all of it or part of it?

18 A Along with multiple other companies, yes.

19 Q And you've done TVT-O removal surgeries, I'm assuming?

20 A Just portions. Just, again, the exposed area.

21 Q But you've done explant surgeries based on complications
22 caused by TVT-O; is that fair? Not caused -- strike
23 that. I know you probably aren't going to like that
24 word.

25 You've done remove- -- you've done explant surgeries

1 of TVT-Os due to complications; correct?

2 MR. KOOPMANN: Objection. Form.

3 THE WITNESS: I have removed sections

4 of TVT-Os for exposure. I can't remember any for any

5 other reason.

6 Q (By Mr. DeGreeff) And is that something you track?

7 A Oh, I -- well, I track all my patients. I see them -- I

8 try to see them on an annual basis, and if they don't

9 agree, I try to make it every other year.

10 Q So do you have something in your office where you track

11 the reason for each removal and what product it is you're

12 removing?

13 A Their medical records.

14 Q Is that a list you would keep in your office somewhere?

15 A It's one I could retrieve.

16 Q So you have a list currently kept in your office of the

17 product you removed and with -- with the reason for

18 removal?

19 A No, I don't have a list.

20 Q And how many TVT-O removal surgeries have you done?

21 A Well, partial TVT-O, I would say a half dozen maybe.

22 Q What about TVT-R?

23 A Same. About a half dozen.

24 Q What about TVT-S?

25 A Maybe three or four.

1 Q So in your entire time working with transvaginal mesh,
2 between TVT, TVT-O, and TVT-S, you believe you've only
3 done 15 to 16 removal surgeries?

4 A I'm sure I've removed 35, 40 other products that are
5 either transobturator or retropubic slings.

6 Q So you've only done 50 total removal surgeries in your
7 time working with transvaginal mesh?

8 A Do you -- are you including POP repair, like Prolift or
9 elevate, Apogee, Perigee, the other products?

10 Q Well, I was asking specifically about TVT, but sure, we
11 can talk about those too.

12 A I mean, I don't keep numbers of it, but I've removed each
13 of those products in the past.

14 Q That was going to be my question. Where's the tracking
15 data on TVT-Rs that were removed, on the number of
16 explants you've done?

17 A What do you mean by "tracking data"?

18 Q Is that something you keep track of in your office?

19 A No, I don't keep track of the numbers.

20 Q How long have you been doing removal surgeries? When did
21 you first start doing them?

22 A Well, again, when you use the word "removal," I'll take
23 out a specific area that may be exposed, or if there's a
24 specific trigger point area of pain, I'll remove that
25 part.

1 Q Are those included in the six, six, and three?

2 A Yes. But I mean, the -- it's -- these numbers are not --
3 are not exact, by any means. I don't keep a log of them.

4 Q Okay. How many days a week do you operate, Doctor?

5 A Well, I don't know what you mean by operations. I do
6 operations on Wednesdays in the hospital. I do
7 operations on Tuesdays in my surgery center. And I do
8 procedures on Mondays, but they could be any day of the
9 week. I could do them night, weekend. So it varies on a
10 week-to-week basis.

11 Q So you don't have certain designated surgery days or
12 times?

13 A I do. Wednesdays for surgeries at the hospital, and
14 Tuesdays in my surgery center.

15 Q Okay. And do you do them all day, or what's the --

16 A Depends on how many. As little as two or as many as all
17 day.

18 Q Okay.

19 A Into the night.

20 Q And we already talked about the fact that 50 percent of
21 your practice is with men; right?

22 A Yes.

23 Q What percentage of your practice is related to treatment
24 of stress urinary incontinence and POP?

25 A Before the mesh litigation, it was at least 50 percent of

1 my entire practice was. At that point I was probably
2 seeing one-third males and two-thirds females. But
3 because of the shrinking volume of women who seek care
4 for these problems, I do less and less each year.

5 Q And what percentage of your practice is related to
6 treating TVM complications?

7 A Oh, less than 1 percent.

8 Q What percentage of your practice is related to the
9 surgical treatment of TVM complications?

10 A Oh, I'd say less than 1 percent at this point. I don't
11 see them that often.

12 Q Doctor, do you do anything within your office to track
13 what percentage of the women that you do implants in are
14 lost to follow-up?

15 A No.

16 Q Do you know what the national average is?

17 A No.

18 Q Do you know what the national average is on complications
19 related to following implant surgeries with TVM?

20 A Oh, there's several papers that provide those numbers.

21 Q Certainly greater than 1 percent, isn't it?

22 A I think it's about 3 and a half percent.

23 Q So you believe 3 and a half is the rate?

24 A One recent paper I reviewed, that was the rate of
25 complications that required something to be done.

1 Q Ever seen any others that's different?

2 A Oh, it's all -- it depends on what study and what cohort.

3 If you happen to be a referral center, you're going to

4 see a lot more because a lot of gynecologists aren't

5 comfortable with doing repairs or revisions.

6 Q And a lot of patients aren't comfortable going back to

7 the person who put in an implant that gave them

8 complications; fair?

9 A That's -- complications in general, for all of medicine,

10 a lot of times patients have unrealistic expectations and

11 will go elsewhere when they don't have exactly the

12 outcome that they want. That's very common, not just in

13 this.

14 Q Okay.

15 A It's common with all complications.

16 Q So it's typical for anybody -- any surgeon to have a

17 significant loss to follow-up; is that fair?

18 A It really -- it depends on what community you're in. If

19 there are -- if you're in a smaller community and there's

20 less choices of where to go, a lot of times, if a patient

21 has a complication and doesn't see you, they'll see one

22 of your colleagues, and they'll -- we can discuss it,

23 they'll -- you'll find out about it. There's many a time

24 where I've called a physician to tell them that a patient

25 of theirs came in and this was their concerns.

1 resolve in some patients, is a risk associated with TVT
2 devices?

3 A It's associated with all pelvic surgery, whether a device
4 is used or not.

5 Q Do you agree that it's associated with TVT devices?

6 A Directly, I can't prove that it's directly associated.

7 Q You agree that chronic pain in the groin, thigh, leg,
8 pelvis and/or -- pelvic and/or abdominal area is a risk
9 associated with TVT devices?

10 A Slings that go through muscle can cause some -- chronic
11 pain. Rarely, but can cause chronic pain, and through --
12 you're talking about transobturator. There's some thigh
13 pain associated regardless of what product is used. It's
14 a very small number.

15 Q Do you agree with the statement that chronic --

16 A What I can't -- what I can't agree on is if it caused
17 chronic pain, why wouldn't every case you do result in
18 chronic pain? The few cases that patients have chronic
19 pain after a pelvic surgery, I can't identify a specific
20 cause of it.

21 Q Doctor, do you agree one or more revision surgeries is a
22 risk associated with TVT devices?

23 A It's a risk, yes. A low risk, but it is a risk.

24 Q Agree that TVT removal may be needed, and that removal
25 may require significant dissection?

1 A Depending on the cause, it's a possibility.

2 (Discussion off the record.)

3 EXAMINATION

4 BY MR. KOOPMANN:

5 Q Dr. Grier, you reviewed case-specific medical records in
6 connection with forming your opinions on the cases in
7 which you were asked to form case-specific opinions;
8 correct?

9 A Yes, yes.

10 Q And you reviewed those records before you drafted those
11 reports; correct?

12 A Yes.

13 Q The reliance list that Counsel was asking some questions
14 about, did you come up with the title of that document?

15 A No.

16 Q Okay. Do you use the term "reliance list" in your
17 practice?

18 A Not at all.

19 Q Is it your understanding that that's a list of materials
20 that one of the law firms involved in this litigation has
21 sent you over the years?

22 A Yes.

23 Q And in your reports regarding the TVT and TVT-O
24 midurethral slings that we've marked as Exhibit 14, and
25 you report regarding the TVT-Secur slings, did you cite a

1 number of articles and position statements and
2 peer-reviewed literature and things like that?

3 A Yes, I did.

4 Q Okay. And are those the materials that you're primarily
5 relying on in support of your opinions regarding --

6 A Yes.

7 Q -- these devices?

8 A Yes.

9 Q The FDA guidance document that some questions were asked
10 about very early in the deposition, that's something that
11 you considered in forming your opinions, but it isn't all
12 you considered in judging the adequacy of the
13 instructions for use for the TVT, TVT-O, and TVT-Securs;
14 correct?

15 A That's correct.

16 Q You also considered your use of those products throughout
17 the past?

18 A Yes.

19 Q And you considered the sort of results that you achieved
20 in treating patients with those products; correct?

21 A Yes.

22 Q Did you also consider the complications that you saw
23 develop in your practice from your use of those products?

24 A Yes.

25 Q And all of that went into forming your opinions regarding

1 the adequacy of the warnings in --

2 MR. DEGREEFF: Objection. Form.

3 Q (By Mr. Koopmann) -- in the IFUs for the TVT, TVT-O, and
4 TVT-Secur?

5 A That's correct.

6 MR. DEGREEFF: Object to the form.

7 Q (By Mr. Koopmann) And did your analysis and your reading
8 of the literature that you cited in your reports for the
9 TVT, TVT-O, and the TVT-Secur, and the efficacy and
10 complications discussed in that literature, also go into
11 your analysis of the adequacy of the warnings in the IFUs
12 for the devices we're here to talk about today?

13 MR. DEGREEFF: I'm going to object to
14 form. Do you just want to give me a running objection on
15 leading?

16 MR. KOOPMANN: Sure.

17 MR. DEGREEFF: Okay. Running
18 objection on the fact that all of these questions are
19 leading.

20 THE WITNESS: Yes. I considered
21 all -- all that information in -- in determining what I
22 think is appropriate for the IFU.

23 Q (By Mr. Koopmann) And the opinions that you set forth in
24 the reports we've marked as Exhibit 14 and 15 regarding
25 the TVT, TVT-O, and TVT-Secur slings, you hold those

1 opinions to a reasonable degree of medical certainty?

2 A Yes.

3 Q You don't hold yourself out to the community as a design
4 expert; is that fair?

5 A That is fair.

6 Q But are you an expert in urologic surgery?

7 A Yes.

8 Q And are you an expert in the materials used in urologic
9 surgery?

10 A Yes, I am.

11 Q And you don't hold yourself out to the community as a
12 warnings expert; correct?

13 A No, I don't.

14 Q But you've used a lot of medical devices throughout your
15 career?

16 A Yes.

17 Q Dozens, certainly?

18 A Yes.

19 Q Hundreds?

20 A Yes.

21 Q And before you use a medical device, you read the
22 instructions for use accompanying the device?

23 A I do.

24 Q And after treating patients with devices, you get a sense
25 of what sort of complications you see?

1 A Yes.

2 Q Okay. And you factored in all of that experience with
3 the TVT, TVT-O, and TVT-Secur slings in forming your
4 opinions about the warnings accompanying those devices?

5 A I have.

6 Q You've been provided -- you were asked some questions
7 earlier about being provided articles, including some of
8 the articles we've got in front of us here today. But
9 did Ethicon provide -- or Ethicon's counsel provide all
10 of these articles the first time that you saw them, or
11 did you read them in the course of your reading as a
12 surgeon?

13 A Oh, many of them I read in the course of my reading.

14 Q You were asked some questions about Professor Ulmsten and
15 payments that he's received. Has Professor Ulmsten's
16 data regarding the TVT sling been reproduced by many
17 other studies?

18 A Yes, it has, all around the world. It's the most studied
19 of all the pubovaginal slings, the urethral synthetic
20 slings.

21 Q Do you practice evidence-based medicine?

22 A I do.

23 Q And what does that mean?

24 A That means what I choose to provide for my patients has
25 scientific scrutiny and is as safe and efficacious as

1 what is the standard of care.

2 Q And are there different levels of evidence?

3 A There is different levels of evidence. From the bottom,
4 which is anecdotal reporting, to the top, which is, say,
5 Cochrane review, meta-analysis, systematic reviews.

6 Q Where do internal company emails fall on the hierarchy of
7 levels of evidence?

8 A They don't fall at all, in any of it.

9 Q Where do failure modes and effects analyses fall in the
10 hierarchy of levels of evidence?

11 A They don't fall at all in the levels of evidence.

12 Q The opinions that you've expressed in your reports
13 regarding the safety and efficacy of the TVT, TVT-O, and
14 TVT slings, are those opinions based in part on your
15 education, including your medical school and residency?

16 A Yes.

17 Q Is it also based on continuing ed courses?

18 A Yes.

19 Q Are those opinions about the safety and efficacy of the
20 devices based on your clinical training and experience?

21 A Yes.

22 Q Are those opinions about the safety and efficacy of the
23 devices based on your review of the peer-reviewed
24 literature, book chapters, podium, and poster
25 presentations and abstracts?

1 A Yes.

2 Q Are they also, your opinions, based on professional
3 society position statements?

4 A Yes.

5 Q Are they also based to some extent on ongoing discourse
6 between yourself and your colleagues regarding these
7 devices?

8 A That is true.

9 Q And your opinions are based in part on your review of
10 complications discussed in the literature and those that
11 you've seen in your practice?

12 A Yes.

13 Q Are the complications that you've seen in your practice
14 consistent with the warnings that you see listed in the
15 adverse reactions section of the IFUs for the TVT and
16 TVT-O and TVT-Secur prior to 2015?

17 A Yes, they're consistent.

18 Q Is chronic pain a risk of any pelvic floor surgery?

19 A Yes, it is.

20 Q It is a risk of the Burch procedure?

21 A Yes, it is.

22 Q It is a risk of pubovaginal sling procedures?

23 A Yes, it is.

24 Q Is dyspareunia a risk of any pelvic floor surgery?

25 A Yes.

1 Q And are any complications that occur after any surgery --
2 do they have the potential to be temporary or chronic?

3 A Yes.

4 Q And do any complications that occur following any pelvic
5 floor surgery have the potential to be mild, moderate, or
6 severe?

7 A Yes.

8 Q Do you have an opinion as to whether chronic pain and
9 dyspareunia are common complications with any pelvic
10 floor procedures, that all pelvic floor surgeons are
11 expected to know?

12 A Yes.

13 Q And what is that opinion?

14 A That opinion is very common, and every pelvic floor
15 surgeon knows that it is a possible complication.

16 Q When you were teaching professional education courses for
17 Ethicon, did any of your colleagues ever express any
18 concern about the complications listed in the IFU?

19 A Well, yes, we discussed it. We would discuss it about --
20 just about every meeting.

21 Q Did they express any concerns about the complications
22 they saw listed?

23 A No. They're known and expected.

24 Q How many TVT slings would you say you've implanted, if
25 you could estimate?

1 A Probably 1,500.

2 Q How many TVT retropubics? Let me be more specific.

3 A At least 500.

4 Q And how many TVT-O slings have you implanted, if you
5 could estimate?

6 A Another 500.

7 Q And how many TVT-Secur slings would you say you've
8 implanted?

9 A Oh, probably between 50 and 75.

10 Q How do the complications that you've seen in your
11 practice from the TVT, TVT-O, or TVT-Secur slings compare
12 with the complications reported in the literature?

13 A They're very similar.

14 Q And how do the complications that you've seen -- strike
15 that.

16 Is it basic medical and surgical knowledge that
17 postsurgical pain can be chronic or temporary?

18 A Yes.

19 Q Is it basic surgical knowledge that, when an adverse
20 reaction occurs, further surgery may be required to
21 correct it?

22 A Yes.

23 Q And did you know, prior to ever putting in a TVT, TVT-O,
24 or TVT-Secur sling in a patient, that tissue in-growth
25 would occur in the pores of the sling?

1 A Yes.

2 Q And based on that understanding, did you also have an
3 understanding that if, for some reason, part of that
4 sling needed to be removed, that dissection would be
5 required?

6 A Yes.

7 Q Did you have many patients who experienced no
8 complications in connection with a TVT surgery?

9 A Yes.

10 Q And is the same true for TVT-O surgeries?

11 A Yes.

12 Q And is the same true for TVT-Secur surgeries?

13 A Yes.

14 Q When you did have a patient that received one of those
15 slings who had a complication, did you treat those
16 complications?

17 A Yes.

18 MR. DEGREEFF: I hope so.

19 Q (By Mr. Koopmann) And you were asked some questions
20 earlier about follow-up of your patients in your
21 practice; is that right?

22 A Yes.

23 Q From time to time, patients don't return to you; that's
24 true?

25 A That is true.

1 Q Okay. And that's true of any doctor, presumably?

2 A It is true of all of us, yes.

3 Q When patients go to other doctors after they have a
4 complication following one of your surgeries, do you
5 often learn about the fact that they went to another
6 doctor?

7 A Yes.

8 Q And how do you do that?

9 A They usually out of courtesy will call me, or if the
10 reverse is true, I will call them.

11 Q Can you think of a single randomized control trial that
12 says the TVT mesh degraded or was cytotoxic?

13 A No.

14 Q And does that apply to the TVT-O sling mesh and the
15 TVT-Secur mesh?

16 A I know of no randomized control trials that show any
17 degradation in any of the mesh products.

18 Q They all have the same mesh; right?

19 A For this line of -- for Ethicon, yes, they're all the
20 same weave, same monofilament.

21 Q For those company documents that you were provided and
22 read, did any of them change your opinions that you
23 formed based upon the peer-reviewed literature that
24 you've reviewed and your experience using the slings?

25 MR. DEGREEFF: I'm going to object to

1 the form. He said he didn't read any review.

2 THE WITNESS: No, I didn't -- none of
3 them changed my opinions.

4 Q (By Mr. Koopmann) And while Ethicon's counsel may have
5 sent you some articles in the course of your work in this
6 litigation, did you also do your own searches for
7 articles and literature?

8 A Yes.

9 Q You don't think chronic pain occurs with any of the TVT
10 family of products due to any defect in the mesh;
11 correct?

12 A That's correct.

13 Q You said that, with respect to -- I think it was
14 stiffness, you said there was a point at which you would
15 see diminishing returns if you had a very elastic sling.

16 What did you mean by that?

17 A Well, if --

18 MR. DEGREEFF: I'm going to object to
19 form. I think that misstates.

20 THE WITNESS: Do I answer?

21 Q (By Mr. Koopmann) Yes.

22 A So if a mesh is too soft and has very, very little
23 stiffness or integrity, it no longer supports the tissues
24 that it's -- that it's designed to support.

25 Q Okay. Is it more lucrative for you to do surgery or to

1 give lectures for device companies?

2 A To do surgery and be in the office.

3 Q So why is it that you've devoted a significant amount of
4 time to giving lectures for device manufacturers or
5 pharmaceutical manufacturers?

6 A Because I enjoy teaching, and I like the collaboration
7 with other physicians around the country, and I find it
8 to be professionally enhancing.

9 Q In what way?

10 A Well, because I've developed a network of friends around
11 the country, of colleagues that I can call if I have a
12 problem with a particular patient. Some of the brighter
13 minds that are in our profession. And it also -- it
14 requires me to stay vigilant in terms of training and
15 study.

16 Q Counsel asked a question about RCTs that have the primary
17 end point of safety regarding the TVT.

18 My question for you is, do all or almost all of the
19 RCTs that you have reviewed on the TVT and TVT-O and
20 TVT-Secur products discuss complications?

21 A Yes. It may not be the primary outcome, but every one of
22 them comments on percentages of complications, adverse
23 outcomes, and issues about pain.

24 Q You were asked some questions about chronic pain
25 associated with the TVT sling, and one of the articles

1 that you had out a few minutes ago was this Tommaselli
2 systematic review and meta-analysis.

3 A Yes.

4 Q That's an article that you reviewed and relied on in
5 forming your opinions?

6 A Yes.

7 Q And in that study, there were 3,974 retropubic TVT -- I'm
8 sorry -- retropubic sling patients?

9 A Yes. And -- well, it was retropubic and transobturator,
10 total.

11 Q Right. But if you look at Table 3 of that study --
12 Table 3.

13 A Got it.

14 Q There were 3,974 total retropubic patients in that study?

15 A Yes.

16 Q And then there were a total of 2,432 transobturator
17 patients?

18 A That's correct.

19 Q And then on the next page, from the right-hand column, it
20 talks about tape-related long-term complications?

21 A Yes. It was --

22 Q And they say there, "Persistent or chronic pain was
23 reported by 13 patients for the retropubic midurethral
24 sling group and 30 patients for transobturator
25 midurethral sling patients"; correct?

1 A Yes.

2 Q And so 13 patients --

3 A Over 3974.

4 Q -- divided by 3974 is a rate of chronic or persistent
5 pain of .3 percent; correct?

6 A That's correct.

7 Q And for 30 patients with the transobturator midurethral
8 slings, divided by 2,432 patients with transobturator
9 midurethral slings, that would yield a persistent or
10 chronic pain rate of 1.2 percent; correct?

11 A Yes.

12 Q One of the articles you have in your binder is an article
13 by Jonsson-Funk, et al.?

14 A Yes.

15 Q That study looked at 188,454 women who underwent a
16 midurethral sling procedure?

17 A Yes.

18 Q And that study showed the nine-year cumulative risk of
19 sling revision or removal was 3.7 percent?

20 A Yes. Over nine years.

21 Q And they found that the nine-year risk of sling revision
22 removal for mesh erosion was 2.5 percent; right?

23 A Yes.

24 Q You've got a study here by Cecile Unger. Is that a study
25 that you reviewed and relied on in forming your opinions

1 in this case?

2 A Yes.

3 Q And did you also review and rely on the Jonsson-Funk
4 study in forming your opinions in these cases?

5 A The previous study, yes.

6 Q In that Unger study, they looked at 3,307 women who
7 underwent sling placement; is that right?

8 A Yes.

9 Q And they found that 89 women underwent sling revision?

10 A Yes. 2.7 percent.

11 Q And if you do the math there, the rate of sling revision
12 for erosion was 0.57 percent?

13 A That's right.

14 Q And the rate of --

15 A Pain is 0.21 percent.

16 Q The rate of vaginal pain or dyspareunia causing sling --
17 or necessitating sling revision?

18 A Yes.

19 MR. DEGREEFF: Can I see those,
20 Doctor, the ones you just spoke about?

21 THE WITNESS: Oh, it was this one
22 here.

23 MR. DEGREEFF: Is this the only one
24 you were just talking about, or was there another one?

25 THE WITNESS: No, that was Funk I

1 think you had there.

2 MR. DEGREEFF: Tommaselli, what was
3 the other one?

4 THE WITNESS: Jonsson-Funk.

5 MR. DEGREEFF: Thank you.

6 THE WITNESS: This is Welk.

7 Q (By Mr. Koopmann) You also reviewed a study by Welk and
8 relied on that in forming your opinions in these cases?

9 A Yes.

10 Q And this study was a population-based retrospective
11 cohort study that included all adult women undergoing an
12 incident procedure for SUI with synthetic mesh in
13 Ontario, Canada, from April 1st, 2002, through
14 December 31, 2012; is that right?

15 A Yes.

16 Q And the number of those women was 59,887?

17 A Yes.

18 Q And the author's conclusion was that ten years after SUI
19 mesh surgery, 1 of every 30 women may require a second
20 procedure for mesh removal or revision?

21 A That's their conclusion, yes.

22 Q So turn to Page E-3, the primary analysis section. It
23 said, overall 1,307 women, or 2.2 percent underwent mesh
24 removal or revision a median of 0.49 years after
25 receiving a mesh implant for SUI. The sling complication

1 was treated by the same surgeon responsible for the
2 original procedure in 812 of the 1,307 cases, which was
3 62.1 percent; is that right?

4 A Correct. Yes.

5 Q You also had a study by Nguyen; is that right?

6 A John Nguyen, yes.

7 Q Nguyen. And that's a study that you relied on in forming
8 your opinions in these cases?

9 A Yes.

10 Q And in this Nguyen study, they looked at all female
11 members of Kaiser Permanente, Southern and Northern
12 California and Hawaii, who underwent sling procedures or
13 pelvic organ prolapse surgeries using implanted grafts of
14 mesh between September 1, 2008, and May 31, 2010; is that
15 right?

16 A Correct.

17 Q And they looked at 3,747 sling patients; is that right?

18 A Yes.

19 Q And 30 of the 3,747 experienced a vaginal mesh erosion?

20 A Yes.

21 Q And that was a 0.8 percent rate for erosions?

22 A That's correct.

23 Q One of the articles you had earlier was an article by
24 Schimpf, et al.; is that right? It's right here.

25 A Okay.

1 Q And that Schimpf study was a systematic review and
2 meta-analysis of randomized control trials from 1990
3 through April 2013, with a minimum of 12 months of
4 follow-up?

5 A Yes.

6 Q And the RCTs were comparing the sling procedure for SUI
7 to another sling or Burch urethropexy?

8 A Correct.

9 Q And they looked at full-length midurethral slings like
10 the TVT and TVT-O?

11 A Yes.

12 Q And they looked at single-incision slings like the
13 TVT-Secur?

14 A Correct.

15 Q And if you look at Table 1 on Page 71.E5, they list in
16 Table E1 the randomized control trials looking at
17 mini-slings versus any other sling; right?

18 A Yes.

19 Q And all of those mini-sling studies that they looked at
20 studied the TVT-Secur except one; is that right?

21 A Yes.

22 Q And then in Table 3 of that study, they look at the rates
23 of adverse events by sling type analyzed from randomized
24 control trials, and included adverse event studies; is
25 that right?

1 A Correct.

2 Q And they compare, when possible, transobturator slings
3 like the TVT-O, mini-slings like the TVT-Secur,
4 retropubic slings like the TVT retropubic --

5 A Yes.

6 Q -- and the Burch procedure and pubovaginal sling
7 procedures; right?

8 A Yes.

9 Q And is this table something that you reviewed and relied
10 on in forming your opinions in this litigation?

11 A I have.

12 Q And the author's conclusion with respect to the
13 midurethral slings versus the Burch procedure, was that
14 they suggested either intervention based on the cure
15 rates -- the objective cure rates and said the decision
16 should balance on -- balance potential adverse events and
17 concomitant surgeries; right?

18 A Yes.

19 MR. DEGREEFF: I don't have anything
20 from Exhibit 4 right here, do I?

21 MR. KOOPMANN: I don't think so.

22 Q (By Mr. Koopmann) Another study you have in your binder
23 for the TVT and TVT-O general report is a study by
24 Mohamed Abdel-Fattah; is that right?

25 A Yes.

1 Q And that study looked at -- their objective was to
2 determine the lifetime risk of undergoing pelvic floor
3 surgery in a cohort of U.K. parous women, and the
4 reoperation rates for pelvic floor surgery?

5 A Yes.

6 Q And they ended up looking at 34,631 women?

7 A Yes.

8 Q If you'll turn to Page 5, they talk about some risk
9 factors for reoperation?

10 A Yes.

11 Q And they found that the -- that 8.8 percent of the women
12 studied had at least one repeat urinary incontinence
13 surgery?

14 A Yes.

15 Q And then they also indicate on the right-hand column that
16 the reoperation rate for urinary incontinence was
17 3.2 percent in the --

18 A In the midurethral group.

19 Q In the midurethral sling group; right?

20 A Yes.

21 Q And it was 10.7 percent in the abdominal retropubic
22 surgery group?

23 A Yes.

24 Q Is that a Burch procedure?

25 A That's exactly what that is.

1 Q In your TVT-Secur general report binder, you have a
2 systematic review and meta-analysis by Colin Walsh; is
3 that right?

4 A Yes. Yes. 2011?

5 Q And that study looked at -- well, it was published in
6 2011; correct?

7 A Yes.

8 Q And it looked at 1,178 women who received the TVT-Secur?

9 A Yes.

10 Q And that was in ten studies?

11 A Ten studies.

12 Q And they found both the objective and subjective cure
13 rate at 12 months was 76 percent?

14 A Yes.

15 Q And they found a 2.4 percent incidence of mesh exposure
16 in the first year?

17 A Yes.

18 Q And a 1 percent rate of dyspareunia?

19 A Yes.

20 Q And a return to theater for complications rate of
21 0.8 percent?

22 A Yes.

23 Q Is this a study that you reviewed and relied upon in
24 forming your opinions about the TVT-Secur sling?

25 A Yes.

1 Q Did you also review a study by Mohamed Abdel-Fattah,
2 which was a meta-analysis regarding single-incision
3 mini-slings?

4 A Yes. But let's find it. Oh, here it is. No. 1. Yes.

5 Q In that study, they looked at a total of 758 women in
6 nine randomized control trials with a mean follow-up of
7 nine and a half months?

8 A Yes.

9 MR. DEGREEFF: Hey, Barry, I'm going
10 to have to object. I mean, all you're doing is sitting
11 here reading documents to him. I mean, if you want to
12 ask him questions about the documents, that's fine, but I
13 feel like you're just reading them to him. I think
14 that's leading.

15 Q (By Mr. Koopmann) Single-incision midurethral slings
16 were associated with significantly lower patient reported
17 and objective cure rates at 6 to 12 months compared with
18 standard midurethral slings.

19 Is that what it reports?

20 A And that was my experience in a study that I contributed,
21 that there was an early -- less pain initially postop,
22 but at the one-year mark was the same as the longer
23 slings.

24 MR. DEGREEFF: Objection. Form.

25 Q (By Mr. Koopmann) Then on Page 471, they note that the

1 single-incision midurethral sling meta-analysis was
2 possible for studies comparing TVT-Secur versus standard
3 midurethral slings; right?

4 A Yes.

5 MR. DEGREEFF: Objection to form.

6 Q (By Mr. Koopmann) And they noted that a trend towards
7 lower rates of patient reported success and objective
8 cure with the TVT-Secur was seen; however, it did not
9 reach statistical significance. Is that right?

10 A Yes.

11 MR. DEGREEFF: Objection. Form.

12 Q (By Mr. Koopmann) And what does that mean, that it did
13 not reach statistic significance?

14 MR. DEGREEFF: You've got to let me
15 get my objections on the record before you answer,
16 Doctor.

17 THE WITNESS: Well, what it means is
18 that --

19 MR. DEGREEFF: Objection. Form.

20 THE WITNESS: -- there wasn't a
21 statistical difference that was enough to be means tested
22 that it was significant. The P testing was not high
23 enough to -- to say that there's a delta here where Secur
24 was different than the standard midurethral sling.

25 Q (By Mr. Koopmann) Okay. And then in the right-hand

1 column under Quality of Life, it indicates that there was
2 a trend towards better quality of life score in the
3 standard midurethral sling group, but it was not
4 statistically significant; is that right?

5 A Yes.

6 MR. DEGREEFF: Objection for form.
7 And just to be clear, is my running objection on form
8 still going for leading?

9 MR. KOOPMANN: I thought it ended
10 because you started objecting again to leading.

11 MR. DEGREEFF: Well, I actually -- I
12 think what happened is that I forgot that we had a -- we
13 had an agreement that I could -- that it was -- I had a
14 running objection. So if my running objection is still
15 in place, then I'll stop saying objection to form on
16 everything.

17 MR. KOOPMANN: I'll put it back in
18 place now.

19 MR. DEGREEFF: Okay. Thanks.

20 Q (By Mr. Koopmann) So does that basically mean that the
21 quality of life scores between the standard midurethral
22 slings and single-incision midurethral slings was no
23 different?

24 A They're -- they're close enough that they are the same.

25 Q And you've reviewedTVT-Secur-related literature,

1 including randomized control trials, that were both
2 favorable regarding the sling, and unfavorable?

3 A That's correct.

4 Q Okay. And you factored all of that in, in forming your
5 opinions about the device?

6 A Yes.

7 MR. JONES: Could we see that one,
8 that Abdel-Fattah?

9 MR. KOOPMANN: Here, I think I've got
10 copies.

11 MR. DEGREEFF: Do you have copies of
12 all of those that you just did that we could have?

13 MR. KOOPMANN: Several.

14 MR. DEGREEFF: Okay.

15 MR. KOOPMANN: Do you want one to take
16 with you?

17 MR. DEGREEFF: Yeah.

18 MR. KOOPMANN: Do you want it now or
19 can I do it after we're done?

20 MR. DEGREEFF: We can do it after
21 we're done. That's fine.

22 MR. KOOPMANN: I think those are all
23 the questions I have for you, Dr. Grier. I may have some
24 more if Counsel has some more.

25 ////

1 (Recess from 9:12 p.m. to
2 9:18 p.m.)

3 FURTHER EXAMINATION

4 BY MR. DEGREEFF:

5 Q Doctor, you mentioned earlier, I believe when Counsel was
6 questioning you, that there was some discord among your
7 colleagues about -- regarding transvaginal mesh.

8 Do you remember giving that testimony?

9 A I don't recall. Discord?

10 Q That's the word you used. Because that's not even a word
11 I would ever come up with.

12 A There's differing opinions in terms of techniques and how
13 to place it and some people will come up with the idea of
14 putting in drains. It's different iterations of the same
15 surgery that may not follow the IFU. So occasionally
16 someone would come up with a concept like that.

17 Q Doctor, you're aware that a number of your colleagues
18 believe that transvaginal mesh is not safe?

19 MR. KOOPMANN: Object to form.

20 THE WITNESS: I think very few of my
21 colleagues agree to that. If you look at the position
22 papers by the different societies, they're -- they feel
23 that it has efficacy and safety, and it should still be
24 used.

25 Q (By Mr. DeGreeff) I guess my question was a little

Douglas Grier, M.D.

1 STATE OF WASHINGTON) I, Cindy M. Koch, CCR, RPR, CRR,
2) ss CLR, a certified court reporter
County of Pierce) in the State of Washington, do
hereby certify:

3
4

5 That the foregoing deposition of DOUGLAS GRIER, M.D.
was taken before me and completed on March 22, 2016, and
thereafter was transcribed under my direction; that the
6 deposition is a full, true and complete transcript of the
testimony of said witness, including all questions, answers,
7 objections, motions and exceptions;

8 That the witness, before examination, was by me
duly sworn to testify the truth, the whole truth, and
9 nothing but the truth, and that the witness reserved the
right of signature;

10

11 That I am not a relative, employee, attorney or
counsel of any party to this action or relative or employee
of any such attorney or counsel and that I am not
12 financially interested in the said action or the outcome
thereof;

13

14 That I am herewith securely sealing the said
deposition and promptly delivering the same to
Attorney David DeGreeff.

15

16 IN WITNESS WHEREOF, I have hereunto set my
signature on the 25th day of March, 2016.

17

18

19

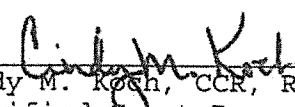
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Cindy M. Koch, CCR, RPR, CRR, CLR
Certified Court Reporter No. 2357

